UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

County of Lake, Ohio v. Purdue Pharma L.P., et al.,
Case No. 18-op-45032 (N.D. Ohio)

County of Trumbull, Ohio v. Purdue Pharma, L.P., et al.,
Case No. 18-op-45079 (N.D. Ohio)

"Track 3 Cases"

MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF THEIR MOTION FOR JUDGMENT AS A MATTER OF LAW UNDER RULE 50(B)

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INTRODUCTION

In response to Defendants' Rule 50(b) motion, Plaintiffs seem to assume that in the course of a trial that "lasted six weeks" and "included the testimony of thirty-four witnesses" and the "admission of hundreds of exhibits," they must have somehow presented a legally viable basis to hold each Defendant liable for public nuisance. Opp. 1. But they are wrong: Plaintiffs produced no evidence that any pharmacist employed by any Defendant in Lake and Trumbull Counties ever knowingly filled even a single illegitimate opioid prescription in violation of 21 C.F.R. § 1306.04(a). This alone requires judgment in Defendants' favor.

Plaintiffs certainly did not show "unlawful conduct" through their made-for-litigation "red flag" protocol, which finds no basis in the Controlled Substances Act ("CSA"). At most, Plaintiffs questioned whether Defendants complied with what their experts consider pharmacy "best practices." But even if those experts could set the standard of care, failure to follow it would only suffice to state a claim for negligence under Ohio law, and therefore qualified nuisance, not the absolute nuisance Plaintiffs tried to prove. And Plaintiffs concede that to establish a CSA violation, they are required to show willful blindness. They have not done so. Plaintiffs are simply wrong when they argue that the alleged collective knowledge of many individuals employed by a *corporate parent* somehow equates to willful blindness of any individual, let alone the *pharmacists dispensing the prescriptions*. That argument contravenes not just longstanding agency principles, but also common sense.

Plaintiffs' failure to prove that any Defendant's dispensing conduct violated the CSA also means that any liability for intentionally distributing opioids is necessarily preempted. To get around that problem, Plaintiffs halfheartedly suggest that certain conduct collateral to dispensing, including various compensation incentives, could somehow provide a basis for liability. Yet Plaintiffs never made this argument at trial or introduced evidence that such policies affected

dispensing behavior generally, let alone led to the improper filling of even one improper prescription.

Finally, Plaintiffs purport to prove causation through nothing more than the "massive amounts" of opioids dispensed in their Counties. But this backdoor attempt at *res ipsa loquitur* causation is simply an indirect challenge to DEA's expert judgment regarding the regulation of opioid medications and is thus preempted by federal law. In any event, Plaintiffs failed to prove that any Defendant's dispensing conduct (which collectively accounted for less than a third of the market in Lake and Trumbull Counties) was a substantial factor in creating an ongoing public nuisance of prescription opioids in the Plaintiff Counties. Plaintiffs' alleged causal chain is even more fatally attenuated by the myriad independent and intervening actors who contributed to the oversupply and diversion of opioid medications. Because Plaintiffs have no response for their insurmountable evidentiary shortcomings on every element of nuisance liability, the Court should enter judgment for Defendants.

ARGUMENT

I. DEFENDANTS CANNOT BE HELD LIABLE FOR AN ABSOLUTE PUBLIC NUISANCE.

Because there is "no legally sufficient evidentiary basis" for a reasonable jury to find that any Defendant acted either (1) unlawfully or (2) intentionally and culpably to cause a public nuisance, the Court should enter judgment for Defendants, even under Plaintiffs' mistaken view of the law and this Court's earlier decisions. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 149 (2000).

A. No Reasonable Juror Could Have Found That Any Defendant Engaged in Unlawful Dispensing Conduct.

Plaintiffs did not present legally sufficient evidence of unlawful dispensing conduct by any Defendant. No evidence introduced at trial showed that any pharmacist employed by any Defendant in Lake and Trumbull Counties ever knowingly filled even one opioid prescription in violation of 21 C.F.R. § 1306.04(a).[1] That conclusively resolves any question of whether Defendants' dispensing practices were unlawful.

Even if Defendants had "an affirmative obligation to protect not only against diversion via theft but also other forms of diversion more broadly" (which Defendants dispute as lacking any basis in the law), Plaintiffs did not introduce any evidence that any Defendant ever violated such obligation with the requisite scienter. *See* Dkt. 3403 at 25; Dkt. 3499 at 5; Dkt. 3439 (Pharmacy Defendants' Motion for Reconsideration or Certification of Order Denying Motion to Dismiss). The Court has held that Plaintiffs must show that each Defendant acted with "deliberate[] ignoran[ce]" or "willful[] blind[ness]," not merely recklessly or negligently. Dkt. 3499 at 7.[2] To

[1] No one disputes that Defendants complied with the physical security and recordkeeping requirements expressly provided by the CSA and its implementing regulations.

[2] Defendants maintain their objections to this interpretation of the applicable legal standard. It is inconsistent with the plain language of the CSA.

be "willfully blind," a defendant must have taken "deliberate actions to avoid confirming a high probability of wrongdoing." *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 769 (2011) (citing G. Williams, Criminal Law § 57, at 159 (2d ed. 1961)). To clear this hurdle, Plaintiffs were required to prove that each Defendant (1) subjectively believed its pharmacists were violating the CSA and (2) intentionally took actions to avoid learning about such violations. *See id.* Yet after six weeks of trial, scores of witnesses, and hundreds of exhibits, Plaintiffs failed to present any evidence showing that any Defendant acted with this requisite scienter.

Plaintiffs rest their case in this regard on the theory that Defendants should be liable for filling prescriptions when "a red flag was or *should have been recognized* at or before the time the controlled substance was dispensed." Opp. 14 (emphasis original). In other words, Plaintiffs argue that the mere fact that Defendants' pharmacists filled prescriptions for opioid medication without specifically documenting the resolution of all of Plaintiffs' 16 made-for-litigation "red flags" is legally sufficient evidence that Defendants violated the CSA.

At most, Plaintiffs' "red-flag" evidence suggests Defendants failed to employ what Plaintiffs' experts would consider pharmacy "best practices." Indeed, at closing argument, Plaintiffs argued to the jury that Defendants should be held liable for not following the optimal "standard of care" and for not being "the leaders out there" in the market. Dkt. 4153 at 7105, 7116 (Nov. 15 trial tr., vol. 28). But failure to comply with a standard of care, without more, can establish only negligence. Under Ohio law, merely negligent acts cannot create an absolute nuisance. *See, e.g.*, *Barnett v. Carr ex rel. Est. of Carr*, No. CA2000-11-219, 2001 WL 1078980, at *10–11 (Ohio Ct. App. Sept. 17, 2001).

More to the point, no reasonable juror could have found the necessary scienter based on Plaintiffs' documentation-of-red-flags theory because those red flags were invented entirely by

Plaintiffs for this litigation. The phrase "red flags" does not appear anywhere in the CSA, any DEA regulation, or any analogous Ohio law or regulation. None of those sources of law contains any list of specific indicators requiring a pharmacist to take certain action—much less the 16 specific "red flags" made up by Plaintiffs' expert. *See* Dkt. 4008 at 1228 (Oct. 8 trial tr., vol. 5). Nor do any of those sources of law contain any requirement to document the resolution of such indicators. The mere fact that an individual pharmacist might not have fully documented how she resolved what Plaintiffs consider to be a "red flag" says nothing about the pharmacist's mental state at the time of dispensing, much less the validity of the prescription itself.

The DEA adjudications that Plaintiffs claim show that the CSA obligated Defendants to impose a mechanized company-wide red-flags screen express no such requirement. DEA adjudications address whether DEA validly found that a pharmacist "has committed such acts as would render his [DEA] registration . . . inconsistent with the public interest." 21 U.S.C. § 824(a)(4). That question is not at issue in this case. Conduct could be short of a violation of the CSA and yet still be "inconsistent with the public interest." (Here, of course, it is undisputed that each Defendant maintained active DEA registrations to dispense controlled substances throughout the entire relevant period, thus implicitly determining that Defendants' registrations *were* in the public interest. Dkt. 4106 at 4547 (Oct. 28 trial tr., vol. 18)). So the body of precedent to which Plaintiffs point is irrelevant.

Each case also involved an individual acting knowingly or with "willful blindness" toward unmistakable signs of diversion, not a mere failure to document resolvable "red flags." In *Medic-Aid Pharmacy; Revocation of Registration*, 55 Fed. Reg. 30,043 (July 24, 1990), DEA concluded that it would be in the public interest to revoke the registration of a pharmacist when an audit revealed that the pharmacist would "dispense the original prescription" for a controlled substance

"as well as all of the authorized refills, on the same day." *Id.* at 30043. Indeed, individuals would "bring prescriptions issued by numerous different doctors for the same controlled substance" to be filled at the pharmacy. *Id.* The same was true in *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy; Revocation of Registration*, 55 Fed. Reg. 47295 (Feb. 9, 1990), where the pharmacist "filled prescriptions for Preludin for many individuals regularly over a period of months notwithstanding Preludin's labelling which warns that the product should not be taken for more than a few weeks." *Id.* at 4730. And in *Jones Total Health Care Pharmacy, LLC v. Drug Enforcement Administration*, 881 F.3d 823, 828 (11th Cir. 2018), the pharmacy's "business was based primarily on sales of controlled substances," 89% of which were "cocktail" drugs, and for which the "markup on the price per pill was over 1,000%." *Id.* at 828.

In each case it was indisputable that the pharmacist—at the very least—took "deliberate actions to avoid confirming a high probability of wrongdoing." *Glob.-Tech Appliances, Inc.*, 563 U.S. at 769. None of the cases turned on the pharmacy failing to use a computerized algorithm to identify and scrupulously document the resolution of a list of 16 "red flags" to determine whether to fill a controlled substance prescription.

The trial testimony confirms that Defendants' pharmacists were under no obligation to document resolution of any red flags, much less those Plaintiffs identified for this litigation. Former DEA Agent Robert Hill confirmed that DEA regulations do not "require the implementation of red flag computer alerts," and that DEA has never "provided official guidance to pharmacies indicating that they should implement red flag alerts in their computer systems." Dkt. 4124 at 6433, 6436 (Nov. 5 trial tr., vol. 24). He also explained that neither the CSA nor its regulations "even discuss[es] the documentation of red flags," let alone requires it, and that DEA has never sent a "Dear Registrant" letter requiring red flag documentation. *Id.* at 6433–35.

Likewise, Ohio Board of Pharmacy Agent Trey Edwards agreed that documentation was not required by law. Dkt. 4111 at 5467 (Nov. 2 trial tr., vol. 21). Indeed, Defendants' clinical expert, Dr. Robert Wailes, testified that applying red flags in a "mechanical" and "absolute" manner was "problematic," because it overrides the "pharmacists' judgment in whether to fill a prescription or not[,]" and thus would "significantly interfere with legitimate patient care and safety." Dkt. 4107 at 4783, 4816 (Oct. 29 trial tr., vol. 19).

No reasonable juror could find that Defendants' pharmacists were willfully blind about opioid diversion simply because they did not take steps they were not required to take. Failing to comply with purported best practices that are identified long after the fact does not suggest scienter. Yet that was the only evidence Plaintiffs offered at trial.

Perhaps recognizing the gaps in their case, Plaintiffs argue that a single individual need not be willfully blind; instead, corporate knowledge can be aggregated to create an apparently irrebuttable presumption of blanket willful blindness. They argue: "Defendants can be shown to have been willfully blind based on what they knew or believed, regardless of whether their pharmacists knew or were willfully blind." Opp. 16. Plaintiffs offer no legal support for that position. Nor does it make any sense, given that "[a] corporation can be held to have a particular state of mind only when that state of mind is possessed by a single individual." *First Equity Corp. of Fla. v. Standard & Poor's Corp.*, 690 F. Supp. 256, 260 (S.D.N.Y. 1988). Instead, Plaintiffs rely on the general proposition that "Defendants . . . are presumed to have the knowledge of the[] employees." Opp. 16. But that generalization sidesteps the crux of the issue here: Whether a corporation's scienter can be measured by taking separate pieces of knowledge from different employees here and there and then cobbling them together to derive an artificial conclusion that no single employee could derive on their own.

The United States Supreme Court has already rejected Plaintiffs' attempt to assign "corporate knowledge" without showing that any single individual possessed such knowledge. "[T]he malicious mental state of one agent cannot generally be combined with the harmful action of another agent to hold the principal liable for a tort that requires both." *Staub v. Proctor Hosp.*, 562 U.S. 411, 418 (2011).[3] That pronouncement in *Staub* followed a legion of lower court decisions saying the same thing. *See In re Omnicare, Inc. Sec. Litig.*, 769 F.3d 455, 477 (6th Cir. 2014) (finding, in the securities context, that a rule against aggregation "protects corporations from liability . . . when one individual unknowingly makes a false statement that another individual, unrelated to the preparation or issuance of the statement, knew to be false or misleading"); *see also, e.g.*, *Chaney v. Dreyfus Serv. Corp.*, 595 F.3d 219, 241 (5th Cir. 2010); *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1273–74, 1276 (D.C. Cir. 2010); *Mizzaro v. Home Depot, Inc.*, 544 F.3d 1230, 1254 (11th Cir. 2008); *Woodmont, Inc. v. Daniels*, 274 F.2d 132, 137 (10th Cir. 1959). Plaintiffs provide no reason to depart from this consensus, except to point out that those cases arose in different contexts from this one. In reality, however, that very diversity of subject matter makes clear that the rule against collective knowledge is based on "general principles of agency" and thus applies in any context. *Chaney*, 595 F.3d at 241.

Plaintiffs faced the burden of showing that Defendants knowingly filled—or, under the Court's rulings, were willful blind to—a particular improper prescription. Because they did not, and do not attempt to say otherwise now, the Court should enter judgment for Defendants.

[3] Plaintiffs are correct that *Staub* recognized that one case involving a federal tort and another case involving a federal crime deviated from this rule. *Staub*, 562 U.S. at 418. Ultimately, however, the Court decided that the governing text aligned most naturally with the common law rule announced by the Restatement of Agency ***against*** aggregate knowledge. *See* Restatement (Second) of Agency § 275, illus. 4 (1958).

B. No Reasonable Juror Could Have Found That Any Defendant Engaged in Intentional, Culpable Conduct.

Plaintiffs also failed to prove that any Defendant engaged in intentional and culpable conduct independent of any violation of the CSA.

As a threshold matter, Plaintiffs have abandoned the position they took at trial for yet another post-hoc rationalization. At closing, Plaintiffs argued that the "intentional element" of the public nuisance test was satisfied because Defendants "weren't accidently dispensing opiates," such as when "someone accidently dump[s] a bunch of lead into the water supply without realizing" it. Dkt. 4153 at 7169 (Nov. 15 trial tr., vol. 28). In other words, Plaintiffs' sole argument under the intentional prong at trial was no more than that Defendants *intentionally dispensed* opioid medications—in other words, that they did not inadvertently dispense opioid medications. There is no legal basis for that proposition, and indeed Plaintiffs now concede that to be liable Defendants must have "intended to bring about the conditions which are in fact found to be a nuisance." Opp. 13.

Plaintiffs do not even attempt to defend the trial theory they actually presented to the jury, which is reason enough to enter judgment for Defendants. Instead, Plaintiffs now argue that they may rely on the intentional prong of the Ohio nuisance test to leverage conduct that "may not be 'fully authorized' under a statute even if it is not explicitly prohibited." *Id.* at 98. This belated rationalization is both legally flawed and unsupported by the record.

To the extent that Plaintiffs seek to hold Defendants liable for dispensing conduct that is "not explicitly prohibited" by the CSA, such machinations would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" and thus would be preempted by federal law. *Arizona v. United States*, 567 U.S. 387, 399–400 (2012). Holding Defendants liable under Ohio public nuisance law for dispensing conduct that Congress considered

and allowed under the CSA—expressly or implicitly—would "skew[]" the "delicate balance of statutory objectives" set by the Act: ensuring the availability of medically indicated therapeutics while, at the same time, limiting the improper use of controlled substances. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). Moreover, under Ohio law, an interference with a public right is "unreasonable" only if Plaintiffs prove that the gravity of their harm outweighs the utility of Defendants' conduct, which involves evaluating the "social value" of such conduct. 1 Ohio Jury Instructions CV 621.05(4), (6). Here, Congress and DEA already have considered the dispensing conduct permitted by the CSA and determined that the social utility of the conduct outweighs the risk of harm.

Plaintiffs alternatively suggest that liability can rest on Defendants' non-dispensing behavior: the effect of compensation policies structured around wait times and prescriptions filled. Opp. 98. Even if such conduct falls outside the scope of the CSA, a jury verdict cannot rest on such thin conjecture. Plaintiffs had to provide legally sufficient evidence that Defendants acted with culpable intent to create an oversupply and diversion of opioids, and that such intentional conduct was a "substantial factor" in causing the alleged harm suffered in Lake and Trumbull Counties as a result of the opioid crisis. Restatement (Second) of Torts § 834 cmt. d (1979). The mere fact that a Defendant used commonplace business practices to reward productivity and to ensure customer satisfaction is hardly evidence that it intended to do so at a reduced standard of care, much less that they set those policies knowing or being substantially certain that they would result in diversion in the Plaintiff Counties. In reality, Plaintiffs introduced no evidence that either of these incentives ever motivated even a single pharmacist to change her dispensing habits, let alone her practice in dispensing opioids. *See* Dkt. 4008 at 200 (Oct. 8, trial tr., vol. 5) (Catizone agreeing that he did not "know one way or another whether or not pharmacists were incentivized"

to overlook red flags). Without more specific evidence, no reasonable juror could conclude that any pharmacist risked losing her professional license and potential criminal liability by filling improper prescriptions for an alleged marginal personal benefit.

Finally, Plaintiffs concede that *Yates v. United States*, 354 U.S. 298 (1957), provides the applicable legal standard in the event of a faulty legal theory subsumed by a general verdict, as was the case here. Opp. 99. "[T]he proper rule to be applied is that which requires a verdict to be set aside in cases where the verdict is supportable on one ground, but not on another, and it is impossible to tell which ground the jury selected." *Yates*, 354 U.S. at 312. So if the Court determines that even one of Plaintiffs' theories is flawed, Defendants are entitled to judgment as a matter of law. Plaintiffs did not prove that any Defendant engaged in any unlawful dispensing conduct. Indeed, Plaintiffs did not prove that any Defendant engaged in any "intentional" conduct beyond intending to dispense FDA-approved opioid medications. And intentional but lawful dispensing conduct cannot form the basis for absolute nuisance liability.

C. No Reasonable Juror Could Have Found That Defendants Caused an Ongoing Public Nuisance in Lake and Trumbull Counties.

Along with the flaws in their substantive legal theory, Plaintiffs introduced no evidence that any Defendant's dispensing conduct was a "substantial factor" in causing a present-day nuisance, let alone that the harm in the Plaintiff Counties was a proximate result of any such conduct. Restatement (Second) of Torts § 834 cmt. d; *id.* §§ 432–33 (1965); *Sutowski v. Eli Lilly & Co.*, 696 N.E.2d 187, 190 (Ohio 1998); *Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990); *Gaines v. Vill. of Wyo.*, 72 N.E.2d 369, 373 (Ohio 1947).

Plaintiffs say that Defendants' failure to identify and refuse to fill illegitimate prescriptions caused their harm. But Plaintiffs introduced no evidence that any pharmacist employed by any Defendant ever filled any such prescription, let alone knowingly filled it in violation of 21 C.F.R.

§ 1306.04(a). To do so, Plaintiffs were required to produce evidence of suspicious prescriptions that (1) were in fact illegitimate, (2) a Defendant could have detected and declined to fill, and (3) a Defendant knowingly filled nonetheless. Plaintiffs offered no such proof. Even if they had, Plaintiffs also did not produce evidence that any such prescriptions were in fact diverted or misused in any way in their counties (or anywhere else)—much less in a way that resulted in injury to the community at large.

Those are critical omissions, but Plaintiffs' trial evidence has other holes, too. Plaintiffs did not prove that each Defendant's dispensing conduct had a "substantial impact" on the opioid crisis. *Schwartz v. Honeywell Int'l, Inc.*, 102 N.E.3d 477, 482 (Ohio 2018); *see Martin v. Cincinnati Gas & Elec. Co.*, 561 F.3d 439, 443 (6th Cir. 2009); Restatement (Second) of Torts § 834 cmt. d; *id.* §§ 432–33. Even setting aside all of the other players and focusing solely on pharmacies, non-defendants accounted for 72% of the market in Lake and Trumbull Counties during the relevant period. WMT-MDL-01541A. And Plaintiffs' own experts and DEA witnesses admitted that the vast majority of the opioid medications Defendants did dispense were for legitimate purposes. Dkt. 4005 at 802 (Oct. 7 trial tr., vol. 4) (Dr. Lembke testifying that "most of the doctors who were writing prescriptions thought they were writing for a legitimate medical purpose"); Dkt. 4023 at 1781 (Oct. 13 trial tr., vol. 7) (DEA testimony that over 99% of prescribers appropriately prescribed opioid medications); Dkt. 4111 at 5470 (Nov. 2 trial tr., vol. 21) (Ohio Board of Pharmacy Agent Trey Edwards testifying that the "vast majority of doctors are writing controlled substances prescriptions legitimately"). Plaintiffs came nowhere near refuting a finding that their alleged harm would have been sustained even absent Defendants' alleged misconduct—a shortcoming they do not even try to address. Restatement (Second) of Torts § 432; *Springsteel*

v. Jones & Laughlin Steel Corp., 192 N.E.2d 81, 87 (Ohio Ct. App. 1963); *Skinner v. N. Mkt. Dev. Auth., Inc.*, No. 96APE12-1655, 1997 WL 381638, at *3 (Ohio Ct. App. July 10, 1997).

Plaintiffs' alleged causal chain was also too attenuated to satisfy proximate cause. Plaintiffs' alleged harms "could have been caused by many other factors unconnected to [Defendants'] conduct," *City of Cleveland v. Ameriquest Mortg. Sec., Inc.*, 615 F.3d 496, 504 (6th Cir. 2010), making Defendants' role too far remote for liability. For example, drug manufacturers (e.g., Purdue, Cephalon, Janssen, Endo, and Mallinckrodt) allegedly changed the standard of care for pain treatment by misrepresenting the dangers and effectiveness of opioids, thereby leading DEA-registered and board-of-medicine licensed doctors, with encouragement of the government, to prescribe in unreasonable numbers. *See In re Nat'l Prescription Opiate Litig.*, No. 17-md-02804, 2018 WL 6628898, at *5 (N.D. Ohio Dec. 19, 2018). Even more, those opioid medications were approved by FDA, their production levels were set annually by DEA, and they were distributed by yet another set of actors—principally (on Plaintiffs' own allegations) McKesson, Cardinal Health, and AmerisourceBergen. And that is just to name a few confounding factors that Plaintiffs themselves have alleged.

Plaintiffs also failed to address the several intervening criminal acts between Defendants' conduct and Plaintiffs' alleged harms, *see Cascone v. Herb Kay Co.*, 451 N.E.2d 815, 819–20 (Ohio 1983); *see also* Dkt. 497-1 at 28–29, or that the ongoing public nuisance Plaintiffs seek to abate today is attributable to illicit opioids, rather than prescription opioid medications. Dkt. 4118 at 5983 (Nov. 4 trial tr., vol. 23) (Dr. Murphy testifying, "It's clearly not prescription opioids that have led to the explosion in deaths in this later period. It's not people overdosing on prescription opioids. It's people overdosing on illegal drugs . . . particularly fentanyl."). Even taken collectively, Defendants' Lake County and Trumbull County pharmacies played only a tiny—and

far-down-the-chain—part in the supply chain. At most, then, they could have had only an *indirect* and *remote* connection to Plaintiffs' alleged injuries.

Plaintiffs' counterarguments fail to bridge these gaps. Instead, Plaintiffs simply argue that Defendants can be found liable solely on account of "massive increases in the supply of prescription opioids" "through aggregate proof." Opp. 83–84. But Defendants cannot be found liable simply for dispensing whatever volume of opioid medications Plaintiffs (but not DEA) say are "too many." It is uncontroverted that Defendants only ever dispensed opioid medications approved by FDA. *See, e.g.*, Dkt. 4005 at 796 (Lembke testimony, Oct. 7 trial tr., vol. 4); Dkt. 4023 at 1723 (Rannazzisi testimony, Oct. 13 trial tr., vol. 7); Dkt. 4090 at 4153 (Dr. Keyes testimony, Oct. 26 trial tr., vol. 16). FDA determined that the "benefits of the drugs outweigh its risks," that the drugs are "safe and effective[,]" and that the drugs are "effective to treat" a patient's medical condition. Dkt. 4093 at 4424 (Toiga testimony, Oct. 27 trial tr., vol. 17); *see also* 21 C.F.R. § 314.125; 21 U.S.C. § 355. And it is uncontroverted that DEA regulated the volume of prescription opioids by setting quotas on the amount of prescription opioid medications that could be *manufactured* each year, but places no stricter limit on the amount pharmacies could fill. Dkt. 4023 at 1725–26 (Rannazzisi testimony, Oct. 13 trial tr., vol. 7). Those quotas were designed to "meet the legitimate medical demands without providing excess medication that may be diverted into the illicit market." *Id.* at 1727.

The role of doctors also cannot be overlooked—if they do not write an opioid prescription, then Defendants' pharmacists have no opioid prescription to fill. The mere fact that Defendants dispensed FDA-approved medications pursuant to legitimate prescriptions written by doctors—no matter how big or how small Defendants' overall volume of dispensing might be, either in absolute terms or expressed as a share of the relevant pharmacy market (*i.e.*, collectively less than 28%, at

least 99% of which were legitimate according to Plaintiffs' own experts)—cannot suffice to prove causation. Otherwise, Ohio nuisance law would override the determination of Congress, FDA, and DEA that opioid medications may be lawfully prescribed and dispensed, in contravention of the Supremacy Clause. *See Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982). And, in any event, Plaintiffs produced no evidence that Defendants were principally responsible for "massive increases in the supply of prescription opioids." Opp. 83–84.

Plaintiffs also fail to distinguish the pivotal causation ruling of *State v. Purdue Pharma L.P.*, No. 30-2014-00725287 (Cal. Super. Ct. Orange Cnty. Nov. 1, 2021). There, the California Superior Court dismissed a public nuisance claim against opioid manufacturers because the State of California, acting through various county governments, failed to "distinguish between medically appropriate and medically inappropriate prescriptions" and presented "no evidence that even attempts to quantify how medically inappropriate prescriptions caused or contributed to the opioid crisis." *Id.* at 14, 17. Plaintiffs say this case is different because they "presented ample evidence that Defendants dispensed thousands of red-flagged opioid prescriptions . . . without any evidence that they resolved those red flags prior to dispensing." Opp. 96. But that hardly settles the issue. Plaintiffs' own expert, Carmen Catizone, testified that "just because a prescription flags under one of [his] 16 red flags, that ***does not mean*** that it was written for an illegitimate medical purpose." Dkt. 4008 at 1208–09 (Oct. 8 trial tr., vol. 5) (emphasis added). Plaintiffs failed to show that even a single pill ever left a single Defendant's pharmacy improperly. Just like the State of California, Plaintiffs failed to "distinguish between medically appropriate and medically inappropriate prescriptions." *Purdue Pharma L.P.*, *supra*, at 14. The Court should therefore grant Defendants judgment as a matter of law.

II. PLAINTIFFS' NUISANCE CLAIM FAILS AS A MATTER OF LAW.

Trial evidence aside, Defendants also established several reasons why Plaintiffs' claims are legally deficient—which by definition means Plaintiffs could not provide a legally sufficient evidentiary basis for those claims. Although the Court previously rejected each of these arguments, *see* Dkt. 1203 (Order Denying Track 1B Motions to Dismiss); Dkt. 3403 (Order Denying Pharmacy Defendants' Track 3 Motion to Dismiss), Defendants restated them in their opening brief to preserve them for appeal. Plaintiffs largely responded to these arguments by incorporating their prior briefing as well as the Court's prior rulings on these topics, warranting no further response. Defendants, however, take this opportunity to address two new arguments raised by Plaintiffs.

First, Plaintiffs relegate analysis of the Oklahoma Supreme Court's recent landmark ruling in *State ex rel. Hunter v. Johnson & Johnson*, 499 P.3d 719 (Okla. 2021), to a mere footnote, stressing that it addressed claims against an opioid manufacturer under Oklahoma law. Opp. 103 n.86. But the Oklahoma Supreme Court's decision cannot be so easily ignored. The holding turned on the lack of historical pedigree and policy rationale for "products-based public nuisance claims" unlike the traditional nuisance claims limited "to land or property use." *Hunter*, 499 P.3d at 730. Indeed, the Court's logic did not depend on the position of the defendant in the supply chain; it swept much broader, warning that "[e]xtending public nuisance law to the manufacturing, marketing, and selling of products—in this case, opioids—would allow consumers to 'convert almost every products liability action into a [public] nuisance claim.'" *Id.* at 729–30. And while it is true the Oklahoma Supreme Court applied Oklahoma law, the Court followed "a clear national trend" against such products-based public nuisance claims, citing cases from across the country and reasoning from universal common law principles fully applicable to Ohio nuisance law. *Id.* at 730.

The Oklahoma Supreme Court decision is particularly significant given this Court's ruling upholding a nuisance cause of action under Oklahoma law in the *Muscogee (Creek) Nation v. Purdue Pharma L.P.* matter. In the *Muscogee* case, the Report and Recommendation, as adopted by the Court, *see* Dkt. 1680 (adopting in relevant part Dkt. 1499), incorrectly predicted the Oklahoma Supreme Court's ruling on each of these key arguments. *See In re Nat'l Prescription Opioid Litig.*, No. 17-md-02804, 2019 WL 2468267, at *29 (N.D. Ohio Apr. 1, 2019) (rejecting the products-liability limitation to Oklahoma nuisance law); *id.* (rejecting requirement that defendant have control of the nuisance); *id.* at *30 (rejecting limitation to what constitutes "public right" under Oklahoma law). The Court, moreover, expressly acknowledged that "the claims presented by Plaintiffs and the arguments brought by Defendants" in that case have "many similarities" to the Ohio nuisance claim at issue in the Track 1 and Track 3 cases. Dkt. 1680 at 2. As in the *Muscogee* case, the Court's prior rulings in the Track 1 and Track 3 cases stretch Ohio nuisance law too far.[4]

Second, Plaintiffs cannot evade the primary jurisdiction doctrine. Plaintiffs do not dispute that "Congress entrusted DEA alone with broad discretion to enforce the CSA uniformly," Mot. 37, which means the Court should stay its hand until DEA has had an opportunity to pass upon Plaintiffs' novel theory of the duties that the CSA imposes on Defendants. *See Charvat v.*

[4] Plaintiffs are wrong to claim that *Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136 (Ohio 2002), somehow helps them overcome the problems identified by the Oklahoma Supreme Court. For one thing, both the Ohio General Assembly (through the Ohio Products Liability Act, Ohio Rev. Code Ann. § 2305.10) and the U.S. Congress (through the Protection of Lawful Commerce in Arms Act, Pub. L. No. 109-92, 119 Stat. 2095 (2005) (codified at 15 U.S.C. §§ 7901–03)) abandoned this case as an undue expansion of nuisance doctrine. For another thing, "[t]he involvement of so many independent actors also reveals why [Plaintiffs'] reliance on *Beretta* is misplaced." *Ameriquest*, 615 F.3d at 505. "*Beretta* has key differences"—chief among them that "through the direct action of the gun manufacturers" sued in *Beretta*, and no one else, "a black market for the illegal sale and distribution of firearms" allegedly existed. *Cleveland v. JP Morgan Chase Bank, N.A.*, No. 98656, 2013 WL 1183332, at *6 (Ohio Ct. App. Mar. 21, 2013). Defendants' pharmacies, on the other hand, did not by themselves "create the cocktail of factors that led to" the opioid crisis. *Id.*; *see Ameriquest*, 615 F.3d at 505 (construing *Beretta*).

EchoStar Satellite, LLC, 630 F.3d 459, 466 (6th Cir. 2010). Plaintiffs' arguments to the contrary are meritless in several respects.

Whether Defendants have complied with the CSA is not, as Plaintiffs would have it, "too general" an issue to come within the primary jurisdiction doctrine. Opp. 110. Defendants have articulated the precise question: whether the "Defendants violated the CSA, at the corporate level, by not alerting their pharmacists to certain 'red flags' and requiring them to resolve such flags through documentation." Mot. 32. None of the cases cited by Plaintiffs require any more specificity than that.

Plaintiffs also incorrectly assert that Defendants have not identified "issues for DEA determination that are ones of first impression or are particularly complicated." Opp. 110. But this court itself has already acknowledged that the question of corporate-level dispensing obligations under the CSA *is* a novel question. Dkt. 2966 at 38 (Dec. 4, 2019 case management conf. tr.); *see also* Dkt. 3403 at 24 (the Court stating it is not clear "what a pharmacy-registrant must do with the prescription data it must collect"). Answering that question requires expertise with a complicated statutory and regulatory framework. In any event, there is no novelty or complexity threshold for triggering the primary jurisdiction doctrine. To suggest otherwise, Plaintiffs cite an order from a district court that falls within the Ninth Circuit, Opp. 110, but the Sixth Circuit has explained that the doctrine applies for "a variety of reasons" that are true here, including advancing regulatory uniformity. *Charvat*, 630 F.3d at 466.

Plaintiffs are also wrong that the primary jurisdiction doctrine could somehow be "subject to waiver or forfeiture" because Defendants have not submitted a request for referral. Opp. 111–12. If the conditions for applying the doctrine are met, "courts may raise the doctrine on their own motion" and in fact *should* do so—"even if [the defendant] should choose not to"—where, as here,

the issue implicates the public interest. *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 674 (2003) (Breyer, J., concurring in part and concurring in the judgment); *see also* 33 Wright & Miller, Fed. Prac. & Proc. § 8366 (2d ed. Nov. 3, 2021 update) ("A court may raise the issue of applying primary jurisdiction on its own motion."). Nor can Plaintiffs' related assertion that Defendants have provided "far too little, far too late" on this issue be credited. Opp. 109. Defendants timely raised the primary jurisdiction doctrine in their initial motion for judgment as a matter of law once it became apparent at trial that Plaintiffs' theory of liability depended entirely on proving an underlying violation of the CSA based on an extra-statutory "red flags" theory. *See* Dkt. 4098 at 35.

Finally, contrary to Plaintiffs' assertions, it would be far more efficient to defer to DEA's "special competence" regarding a central legal issue in this case than to press on with a remedies trial and appeals. *Charvat*, 630 F.3d at 466. If the Sixth Circuit later reverses on the question of Defendants' duties under the CSA or determines that DEA should have its opportunity to pass on this question first, proceedings between now and then will have been a waste of time and resources.

CONCLUSION

For these reasons, the Court should grant judgment as a matter of law under Rule 50(b) in favor of Defendants.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that the foregoing document was served via the Court's ECF system on all counsel of record on January 31, 2022.

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